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10/661,400

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J. Christopher Marmo

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IRVINE, CA 92618

EXAMINER

PREBILIC, PAUL B

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/661,400 | Applicant(s) MARMO ET AL. | |
| | Examiner Paul B. Prebilic | Art Unit 3774 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 90,99,187,189,204,205 and 207 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 81-86,89-108,112,113,121-130,132,134-137,140,150,160-171,173,177-180,182-198 and 200-221.

Continuation of Disposition of Claims: Claims rejected are 81-86,89,91-98,100-108,112,113,121-130,132,134-137,140,150,160-171,173,177-180,182-186,188,190-198,200-203,206 and 208-221.

The response filed December 17, 2007 does not at least acknowledge and disclose any copending applications that set forth similar subject matter; see the second paragraph under the "Conclusions" section of the September 13, 2007 Office action. Failure to provide this information may result in the Examiner deeming the response non-responsive in the future.

Election/Restrictions

Applicant's election with traverse of Group III in the reply filed on November 16, 2005 is acknowledged. Also acknowledged is the August 14, 2006 election of (1) collagen other than collagen Type I (claims 190 and 208), (2) recombinant collagen (claim 203), (3) extracellular matrix proteins (claims 184 and 210) and (4) epithelium lifted with vacuum (claims 98 and 164) with traverse.

Claims 90, 99, 187, 189, 204, 205, and 207 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 90, 187 and 205 were also withdrawn because they required searching and examination of the non-elected species. Applicant timely traversed the restriction (election) requirement in the reply filed on August 14, 2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 81-86,89,91-98,100-108,112,113,121-130,132,134-137,140,150,160-171,173,177-180,182-186,188,190-198,200-203,206 and 208-221 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention has been inadequately described because the formation of a pocket and the insertion of a lens clearly require an incision to access the area between the corneal epithelium and Bowman's membrane. An epithelial flap is also created by an incision to separate the tissue layers. Therefore, it is unclear how creating a pocket "without creating an epithelial flap" differs from one creating an epithelial flap to form a pocket for the insertion of a lens. Particularly, the Applicant has failed to adequately describe the limitation "without creating an epithelial flap" such that one could readily distinguish that from creating an epithelial flap since both processes involve separating tissue layers and making an incision.

Upon reviewing the specification, the description of this claim limitation suggests that Figures 7A and 7B show a slit without a flap and that Figures 6A and 6B show a slit with a flap; see the paragraph separating pages 38 and 39 of the present specification. However, the slits of Figure 7A and 8A appear long enough to allow folding back of the top lip upon the adjacent epithelium so the Examiner asserts that one in the art could understand these incisions as forming epithelial flaps. Yet the Applicant is relying on these Figures to show a distinction between the two.

Consequently, based upon this description, it is unclear how a slit must differ between one that is a flap producing slit and a non-flap producing slit. Moreover, the Applicant has failed to provide sufficient guidance to one of ordinary skill as to how to distinguish between a slit that produces an epithelial flap and one that does not.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 81-86,89,91-98,100-108,112,113,121-130,132,134-137,140,150,160-171,173,177-180,182-186,188,190-198,200-203,206 and 208-221 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Due to the uncertainty of the meaning of "without creating an epithelial flap", the claim scope is considered unclear.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 81-85, 89, 91, 92, 94-95, 97 98, 105, 106, 108, 182-183, 185, 188, and 191 are rejected under 35 U.S.C. 103(a) as obvious over Perez (WO 02/06883) in view of Gibson et al (US 5,171,318) or Kern (US 4,676,790) and Simon et al (US 5,547,468) or Hoffer (US 4,636,210). Perez teaches a method of creating a pocket between the

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epithelial layer of a cornea and the Bowman's membrane and then inserting a lens therein before closure thereof; see Figures 5 and page 19, lines 1-16. However, Perez fails to disclose the use of an adhesive to secure the lens in the pocket as claimed and calls separated epithelial layer a flap. Gibson (see column 10, lines 17-44) and Kern (see column 4, lines 25-48) both teach that it was known to secure similar devices within Bowman's membrane with adhesive. Additionally, Simon [see column 8, lines 39-41] or Hoffer [see column 1, lines 51-59] teaches that it was known to make slits in the eye as small as possible to reduce trauma and healing time. Therefore, it is the Examiner's position that it would have been obvious to do the same in the Perez method in order to more securely hold the lens thereof to Bowman's membrane as taught by Gibson or Kern. Additionally, it would have been obvious to make the incision of Perez as small as possible to reduce trauma and healing time as taught by Simon or Hoffer.

With regard to claim 84, Applicants are directed to Figures 46-53 and column 18, line 15 et seq.

With regard to claim 85, it was inadvertently left out of the rejection statement of the previous Office action. However, it should have been included with the first prior art rejection supra. Clearly, the lens is inherently deformed as it is formed particularly when the material is in a semisolid state such deformation would inherently occur due to gravity acting on the device while laying on a solid surface.

With regard to claim 183, the curved surface of the ocular material is the cellular attachment element to the extent required by the claim language.

Claims 96, 100-102, 150, 178, 179 and 184 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perez (WO 02/06883), Gibson, Kern, Simon, and Hoffer as applied to claims 81-84, 89, 91, 92, 94-95, 97, 98, 105, 106, 108, 183, 185, 188, and 191 above, and further in view of Brown et al (US 4,959,353). Perez (WO 02/06883) fails to disclose the application of a healing agent as claimed. However, Brown teaches that it was known to apply a healing agent to the corneal tissue after similar surgical operations; see the title and column 1, lines 15-35. Therefore, it is the Examiner's position that it would have been obvious to apply a healing agent to the cornea in the Perez method in order to promote healing therein.

With regard to claim 100, Applicants are directed to column 4, lines 43-57 of Brown.

Claims 121-123, 126, 132, 140, 160, 163, 164-166, 173, and 192 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perez (WO 02/06883), Gibson, Kern, Simon, and Hoffer as applied to claims 81-84, 89, 91, 92, 94-95, 97, 98, 105, 106, 108, 183, 185, 188, and 191 above, and further in view of Miller (US 6,335,006). Perez (WO 02/06883) fails to disclose the use of a liquid to loosen the epithelial layer as claimed. However, Miller teaches that it was known to use liquids of various types to loosen epithelial layers; see column 1, line 65 to column 3, line 29. Therefore, it is the Examiner's position that it would have been obvious to use the Miller procedure to loosen the epithelial tissue in Perez process for the same reasons that Miller does the same and in order to promote a clean separation of the tissue layers.

Claims 112, 113, 124, 125, 134-137, 161, and 162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perez, Gibson, Kern, Simon, Hoffer, and Miller as applied to claims 121-123, 126, 132, 140, 160, 163, 165, 166, 173, and 192 above, and further in view of Perez (US 2003/0220653). Perez fails to teach the use of a hypertonic solution to loosen the epithelial layer. However, Perez teaches that such solutions were known to the art at the time the invention was made; see paragraph [0150]. Therefore, it is the Examiner's position that it would have been obvious to utilize a hypertonic solution for the loosening procedure of Miller for the same reasons that Perez utilizes the same and in order to prevent the use of toxic residues to the eye tissue that could cause toxicity problems after surgery.

The hypertonic solution subject matter of Perez has an effective filing date of January 17, 2002 based upon provisional application 60/350,003; see paragraphs [0050] to [0052] thereof and see MPEP 2163.03 III that is incorporated herein by reference.

With regard to claims 134-137, Applicants are directed to see paragraphs [0094] to [0105] of Perez.

Claim 171 is rejected under 35 U.S.C. 103(a) as being unpatentable over Perez, Gibson, Kern, Simon, Hoffer and Miller as applied to claims 121-123, 126, 132, 140, 160, 163, 164, 165, 166, 173, and 192 above, and further in view of Peyman (US 2004/0015234). Perez discloses utilizing various instruments to make incisions in the cornea, but fails to teach that use of a microkeratome. However, Peyman ('234) teaches that it was known to utilize a microkeratome to make incisions in similar corneal

procedures in the art. Therefore, it is the Examiner's position that it would have been obvious to utilize a microkeratome to make the incisions of Perez for the same reasons that Peyman ('234) utilizes the same and in order to make a very clean and precise incision as compared to other procedures of the art.

Claim 177 is rejected under 35 U.S.C. 103(a) as being unpatentable over Perez, Gibson, Kern, Simon, Hoffer and Miller as applied to claims 121-123, 126, 132, 140, 160, 163-166, 173, and 192 above, and further in view of Brown (US 4,959,353). Perez fails to disclose the application of a healing agent as claimed. However, Brown teaches that it was known to apply a healing agent to the corneal tissue after similar surgical operations; see the title and column 1, lines 15-35. Therefore, it is the Examiner's position that it would have been obvious to apply a healing agent to the cornea in the Perez method in order to promote healing therein.

Claims 180, 192-196, 200-202, 206, and 209 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perez, Gibson, Kern, Simon, and Hoffer as applied to claims 81-84, 89, 91, 92, 94-95, 97, 105, 106, 108, 183, 185, 188, and 191 above, and further in view of Cumming (US 5,984,914). Perez fails to disclose the use of cooling as claimed. However, Cumming teaches that it was known to cool ablated tissue when forming a pocket to prevent further damage due to heat; see claims 1 and 8 as well as column 3, lines 58-63. Therefore, it is the Examiner's position that it would have been obvious to cool the eye tissue during pocket formation for the same reasons that Cumming did the same.

Claim 211 is rejected under 35 U.S.C. 103(a) as being unpatentable over Perez, Gibson, Kern, Simon, Hoffer and Cumming as applied to claim 194 above, and further in view of Nigam (US 6,361,560). Perez fails to disclose the use of a microkeratome to form the pocket as claimed. However, Nigam teaches that it was known from pockets with microkeratome within the art; see column 1, lines 40-44 and column 3, lines 26-32. For this reason, it is the Examiner's position that it would have been obvious to form the pockets of Perez with a microkeratome for the same reasons that Nigam does the same and because such devices are widely available to an ordinary artisan.

Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over Perez, Gibson, Kern, Simon, and Hoffer as applied to claim 81 above, and further in view of Peyman (US 2004/0015234). Perez discloses utilizing various instruments to make incisions in the cornea, but fails to teach that use of a microkeratome. However, Peyman ('234) teaches that it was known to utilize a microkeratome to make incisions in similar corneal procedures in the art. Therefore, it is the Examiner's position that it would have been obvious to utilize a microkeratome to make the incisions of Perez for the same reasons that Peyman ('234) utilizes the same and in order to make a very clean and precise incision as compared to other procedures of the art.

Claims 197 and 198 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perez, Gibson, Kern, Hoffer, Simon and Cumming as applied to claim 194 above, and further in view of Perez (US 2003/0220653). Perez fails to teach the use of a salt and water solutions to the cornea. However, Perez teaches that such solutions were known to the art at the time the invention was made; see paragraph [0150]. Therefore,

it is the Examiner's position that it would have been obvious to utilize a hypertonic solution for the loosening procedure of Perez (WO) for the same reasons that Perez ('635) utilizes the same and in order to prevent the use of toxic residues to the eye tissue that could cause toxicity problems after surgery.

Claims 186 and 190 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perez, Gibson, Kern, Simon, and Hoffer as applied to claim 81 above, further in view of Isseroff et al (US 2002/0039788). Perez discloses making lenses out of collagen but not out of recombinant collagen as now claimed. However, Isseroff teaches that it was known to make similar corneal repair materials out of recombinant collagen. For this reason, it is the Examiner's position that it would have been obvious to utilize recombinant collagen as the collagen of Perez for the same reasons that Isseroff uses the same or for improved healing properties.

Claims 203 and 208 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perez, Gibson, Kern, Simon, Hoffer and Cumming as applied to claim 194 above, and further in view of Isseroff et al (US 2002/0039788). Perez discloses making lenses out of collagen but not out of recombinant collagen or collagen other than Type I as now claimed. However, Isseroff teaches that it was known to make similar corneal repair materials out of recombinant collagen or collagen other than Type I. For this reason, it is the Examiner's position that it would have been obvious to utilize recombinant collagen as the collagen of Perez for the same reasons that Isseroff uses the same or for improved healing properties.

Claim 210 is rejected under 35 U.S.C. 103(a) as being unpatentable over Perez, Gibson, Kern, Simon, Hoffer and Cumming as applied to claim 194 above, and further in view of Brown (US 4,959,353). Perez fails to disclose the use of growth factors such as healing agents as claimed. However, Brown teaches that it was known to apply a healing agent to the corneal tissue after similar surgical operations; see the title and column 1, lines 15-35. Therefore, it is the Examiner's position that it would have been obvious to apply a healing agent to the cornea in the Perez method in order to promote healing therein.

Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over Perez, Gibson, Kern, Hoffer, and Simon as applied to claims 81-85, 89, 91, 92, 94-95, 97, 105, 106, 108, 183, 185, 188, and 191 above, and further in view of Civerchia (US 4,983,181). Perez fails to disclose the step of removing an old lens and replacing it with a new one as claimed. However, Civerchia teaches that it was known to the art to remove and replace lenses as necessary; see column 7, lines 7-20. Therefore, it is the Examiner's position that it would have been obvious to do the same in the Perez method for the same reasons that Civerchia does the same.

Claims 103 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perez, Gibson, Kern, Simon, and Hoffer as applied to claims 81-85, 89, 91, 92, 94-95, 97, 105, 106, 108, 183, 185, 188, and 191 above, and further in view of Viegas et al (US 5,587,175). Perez fails to disclose the application of a cellulosic agent to the eye as claimed. However, Viegas teaches that it was known to the art to apply cellulose during eye surgery as a way to treat and fill the same; see the abstract and column 5,

lines 53-59. Therefore, it is the Examiner's position that it would have been obvious to apply cellulose to the eye during the Perez method for the same reasons that Viegas does the same.

Claims 212 and 213 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perez (WO 02/06883), Simon et al (US 5,547,468) and Hoffer (US 4,636,210) in view of Viegas et al (US 5,587,175). The teaching of Simon or Hoffer is explained supra and that explanation is incorporated herein by reference. Perez fails to disclose the application of a cellulosic agent to the eye as claimed. However, Viegas teaches that it was known to the art to apply cellulose during eye surgery as a way to treat and fill the same; see the abstract and column 5, lines 53-59. Therefore, it is the Examiner's position that it would have been obvious to apply cellulose to the eye during the Perez method for the same reasons that Viegas does the same.

Claims 127-130, 167-170, and 214-221 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perez, Gibson, Kern, Simon, Hoffer and Miller as applied to claims 121-123, 126, 132, 140, 160, 163, 165, 166, 173, and 192 above, and further in view of Viegas et al (US 5,587,175). Perez fails to disclose the application of a cellulosic agent to the eye as claimed. However, Viegas teaches that it was known to the art to apply cellulose during eye surgery as a way to treat and fill the same; see the abstract and column 5, lines 53-59. Therefore, it is the Examiner's position that it would have been obvious to apply cellulose to the eye during the Perez method for the same reasons that Viegas does the same.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. Simon and Hoffer are utilized to show that making a smaller incision (i.e. not making a flap) would have been obvious to one of ordinary skill in the art.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilit whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilio/
Paul Prebilio
Primary Examiner
Art Unit 3774